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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,611	10/30/2001	Dale L. Boger	TSRI 626. 1D1	1470

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EXAMINER

WRIGHT, SONYA N

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 03/25/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/001,611

Applicant(s)

BOGER, DALE L.

Examiner

Sonya Wright

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 19-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 19-31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/30/01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1 and 19-31 are pending in this application. It is requested that Applicants verify the continuing data for the case and insert the continuing data at the beginning of the specification, after the title.

### ***Election/Restrictions***

Applicants' election with traverse of the process illustrated in Figure 6 for synthesizing Compound 12a in Paper No. 7 is acknowledged. The traversal is on the ground(s) that: The only difference with respect to the processes of synthesizing compounds 12a, 12b, and 12c is the starting material and, in each case, the starting material is an ortho-haloaniline. This is not found persuasive for the following reason. The synthesis of compound 12b cannot be rejoined because Applicant's claims do not embrace the starting material 10b, wherein there is a -CN group on the naphthyl ring. The synthesis of compound 12c cannot be rejoined because compound 12c contains a pyridine ring, and is therefore differs in classification from the compound of 12a. Compound 12c is classified in class 546, subclass 1+ and compound 12a is classified in class 548, subclass 427. Therefore, rejoining the synthesis of compound 12c would be an undue search burden in the examination process. Because these inventions have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicants argue that the synthesis of compounds 12d-12e differ from the process for synthesizing compound 12a only in that condition (c ) is replaced by condition (d). However, the Description of Figures indicates that condition (d) differs

from condition (c ) merely by the use of different solvents and temperature, and the basis reaction mechanism remains the same. This is not found persuasive for the following reason. Compounds 12d and 12e are classified in class 548, subclass 433, and compound 12a is classified in class 548, subclass 427. Rejoining the synthesis of compounds 12d-12e would be an undue search burden in the examination process. Because these inventions have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicants argue that the synthesis of compounds 12f-12g differ from the process for synthesizing compound 12a only in that condition (a) is replaced by condition (b), however, the Description of Figures indicates that condition (b) differs from condition (a) merely by an addition of a catalyst for activating the 1,3-dichloropropene, the basis reaction mechanism remains the same. This is not found persuasive because the to rejoin the process of synthesizing compound 12f would require additional searching in online databases and paper literature and would therefore be an undue burden on the examination process. To rejoin the process of synthesizing the compound 12g would be an undue search burden due to the addition of a catalyst and because the classification of compound 12g differs from the classification of compound 12a. Compound 12g is classified in class 548 and subclass 491 while, as indicated supra, compound 12a is classified in class 548 and subclass 427.

The following generic concept as depicted in claim 1 is identified for examination along with the elected embodiment: R1 and R2 form a fused 6-membered aromatic carbocyclic ring; R3 is BnO-, R4 is MeO-; X is as defined. The remaining subject matter

of claims 1 and 19-31 is withdrawn from further consideration under 37 CFR 1.142(b) as constituting other patentably distinct inventions.

The withdrawn subject matter of claims 1 and 19-31 in their entirety is properly restricted as said subject matter differs in structure and element from the elected subject matter so as to be patentably distinct therefrom, i.e. a reference which anticipated the elected subject matter would not even render obvious the withdrawn subject matter and fields of search are not co-extensive.

Claims 1 and 19-31 in their entirety are objected to as containing non-elected subject matter. This objection may be overcome by limiting the claims to the elected subject matter identified supra.

The requirement is still deemed proper and is therefore made FINAL.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

Claim 1 is directed to a "process for synthesizing a dihydroindole C-ring of a CC-1065/duocarmycin analog". The specification does not reasonably provide enablement for the instantly claimed process.

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. The claims lack positive steps which teach how the process claimed is performed. There is little predictability in the art of which modifications may be made to the processes as claimed in order to prepare the claimed compound. The phrases "synthesizing" and "cyclizing" may encompass a great number of processes, however, without some guidance as to how these processes are performed, there would be little predictability in making the invention as claimed. The level of ordinary skill in the art is high. The skilled artisan would have a numerous amount of modifications to perform in the processes as claimed order to obtain the claimed compound, therefore undue experimentation would be required to prepare the instant compounds which are useful as antitumor antibiotics.

It is suggested that Applicant incorporate positive steps into the process of claim 1, e.g. the process steps described on page 4, lines 19-25 of the specification.

***Claim Objections***

Applicant is advised that should claim 1 be found allowable, claim 21 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim 21 is drawn to a process according to claim 1 wherein, in Step A, the ortho-haloaniline is protected with a BOC group. However, in claim 1, the ortho-haloaniline is protected with a BOC group, therefore, claim 21 is not further limiting of claim 1.

The reference cited on the PTO-892 is included only to show the state of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sonya Wright, whose telephone number is (703) 308-4539. The examiner can normally be reached on Monday-Friday from 8:00 AM - 5:30 PM.

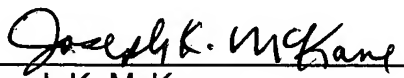
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph K. McKane, can be reached at (703) 308-4537. The Unofficial

fax phone number for this Group is (703) 308-7922. The Official fax phone numbers for this Group are (703) 308-4556 or 305-3592.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-1235.

  
\_\_\_\_\_  
Joseph K. McKane

Supervisory Patent Examiner

Group 1600

Sonya Wright

March 21, 2003